OCT 3 1 2013

4. 510(k) Summary

SUBMITTER:	Altus Partners 5129 West Chester Pike Newtown Square, PA 19073 Phone: 610-355-4156 Fax: 610-300-3049
CONTACT PERSON:	Claudia Hill Product Development Engineer
DATE PREPARED:	October 30, 2013
COMMON NAME:	Pedicle Screw Spinal System
PROPRIETARY NAME:	Altus Spine Pedicle Screw System
PREDICATE DEVICES:	Vertebron PSS Pedicle Screw System (K033352, K043152, K051716, K071376, & K081597)
CLASSIFICATION NAME:	21 CFR §888.3050 Spinal Interlaminal Fixation Orthosis 21 CFR §888.3060 Spinal Intervertebral Fixation Orthosis 21 CFR §888.3070 Pedicle Screw Spinal System
PRODUCT CODES:	MNI, MNH, KWQ, and KWP
DEVICE CLASS:	Class II

DEVICE DESCRIPTION:

The Altus Spine Pedicle Screw System consists of a system of implantable screws to be used with implantable rods for the purpose of aiding in spinal fusion. The Altus Spine Pedicle Screw System attaches to the vertebral body by means of screws to the non-cervical spinal and allows a surgeon to build a spinal implant construct with the intent to stabilize the spinal operative site during the fusion process of bone graft in the disc space. Implantable components are composed of titanium alloy meeting the requirements of ASTM F136. The device is supplied non-sterile and is intended for sterilization by hospital personal.

INDICATIONS FOR USE:

The Altus Spine Pedicle Screw System is a noncervical spinal fixation device intended to provide stabilization of the spinal segments. It is indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft only having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Altus Spine Pedicle Screw System may be used to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

1. Degenerative Spondylolisthesis with objective evidence of neurologic impairment;
2. Fracture;
3. Dislocation;
4. Scoliosis;
5. Kyphosis;
6. Spinal Tumor;
7. Failed previous fusion (pseudoarthrosis).

When used as a non-posterior, non-pedicle anterolateral fixation system the specific indications are:

1. Degenerative disc disease as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies;
2. Spondylolisthesis;
3. Fracture;
4. Dislocation;
5. Scoliosis;
6. Kyphosis;
7. Lordosis;
8. Spinal stenosis;
9. Spinal tumor;
10. Failed previous fusion (pseudoarthrosis)

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The intended use, technological principles, and material of the Altus Spine Pedicle Screw System do not substantially differ from the predicate devices. Cleaning and sterilizating is done in the same manner, and both provide correction and stability during the fusion process of bone fusion. Device samples underwent testing and had comparable performance and function when compared to the predicate device.

SUMMARY OF NON-CLINAL TESTS SUBMITTED:

Dynamic compression bending, static compression bending, and static torsion testings were completed per ASTM F1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy model. All mechanical testing met the predetermined acceptance criteria.

SUBSTANTIAL EQUIVALENCE CONCLUSION:

Testing in accordance with ASTM F1717 was performed and demonstrated that the Altus Spine Pedicle Screw System is substantially equivalent to the currently marketed Vertebron PSS Pedicle Screw System (K033352, K043152, K051716, K071376, & K081597).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 31, 2013

Altus Partners, LLC
Ms. Claudia Hill
Product Development Engineer
5129 West Chester Pike
Newtown Square, Pennsylvania 19073

Re: K132280
Trade/Device Name: Altus Spine Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWP, KWQ
Dated: August 9, 2013
Received: August 12, 2013

Dear Ms. Hill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indications for Use Statement

Indications for Use

510(k) Number (if known): K132280
Device Name: Altus Spine Pedicle Screw System
Indications for Use:

The Altus Spine Pedicle Screw System is a noncervical spinal fixation device intended to provide stabilization of the spinal segments. It is indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft only having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

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9. Spinal tumor;
10. Failed previous fusion (pseudoarthrosis)

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S
(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132280